REMARKS/ARGUMENTS

Reconsideration and withdrawal of the rejections in the outstanding Office Action are respectfully requested in view of the foregoing amendments and the following remarks.

Summary of Status of Amendments and Office Action

In the present amendment, claims 1 and 4-16 are amended. Claim 2 is canceled. Claims 17-19 are added. Therefore, claims 1 and 3-19 are pending in the application, with claims 1 and 6 being independent. Applicants appreciate the Examiner granting a telephone interview with Applicants' representative on June 23, 2005. During the interview, proposed amendments and arguments were presented to the Examiner but the Examiner indicated he would not consider them at that time and that the amendments and arguments should be presented in writing.

Applicants have amended the claims to more clearly recite the claimed subject matter. Support for the amendments is found in the application as filed. In particular, claims 1 and 6 are amended to recite "isolated cytokine," "at least one isolated compound that is a cytokine-inducing agent," and "a microparticle comprising a fragment of solidified tumor tissues or cells, said fragment being of a size so as to allow phagocytosis of the fragment." Dependent claims 9-16 are similarly amended to reflect the amendment of claim 1. Dependent claims 17-19 have been added. Support for these amendments and additional claims is found in the specification, for example, at page 7, line 5, to page 8, line 29, and page 9, lines 4-21. No new matter is added.

Claim Of Priority

Applicants appreciate the acknowledgement of the claim of foreign priority to Japanese Application No. 11-031197, filed February 9, 1999, as well as receipt of the priority document.

Information Disclosure Statements

Applicants express appreciation for the consideration of the Information Disclosure Statements filed on February 27, 2004, July 30, 2002, February 4, 2002, and December 10, 2001, by including initialed copies of the Forms PTO-1449 submitted therewith. Applicants note that although Chinese Application No. 1119459 was crossed out by the Office Action for a lack of an English translation, the English abstract of the application was considered.

Applicants remind the Examiner, that this Chinese document was cited in the Third Supplemental Information Disclosure Statement filed February 29, 2004. A copy of a Chinese Office Action and an English Translation of the Chinese Office Action were submitted as well as an English abstract of the Chinese document. Therefore, in accordance with Patent and Trademark Office procedure, the Examiner should indicated consideration of the Chinese document. Applicants are submitting a Form PTO-1449 listing this document. The Examiner is respectfully requested to forward an initialed copy of the form with the next communication from the Patent and Trademark Office.

Rejections Under 35 U.S.C. 102(b)

Hiserodt

Claims 1-3, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/16238 to Hiserodt et al. ("Hiserodt"). Claim 2 is canceled. Claims 4-5 and 8-16 were not included in the rejection. The Office Action asserts that Hiserodt discloses a vaccine comprising two main components: (1) "a source of tumor antigen", and (2) a stimulated lymphocyte population that allegedly meets the "cytokine-inducing agent" of claims 1, 2, and 6. The Office Action also asserts that the Hiserodt teaches that the vaccine optionally includes additional active components including cytokines (see page 23, lines 5-9).

In regard to the first component, "a source of tumor antigen", the Office Action asserts that "an alternative source of tumor-associated antigen" includes "tumor cell homogenate, detergent lysate, or a purified derivative thereof", (see page 6, lines 38-40), and that "[c]ancer cells for use as tumor antigen source can be...fixed" (see page 15, lines 20-25). The Office Action asserts that the limitation "solidified tumor material" in claims 1 and 3 is interpreted as fixed tumor cells, and that "lysate" is defined as "a state of dispersion...in an aqueous medium such as water, physiological saline" (page 8 of specification).

In regard to the second component, the Office Action asserts that the required stimulated lymphocyte population in Hiserodt allegedly meets the "cytokine-inducing agent" limitation in claims 1, 2, and 6. Figure 6 shows a bar graph of the level of secretion of the cytokines IL-2 and IFN-(gamma) by human alloactivated cell preparations. This alloactivation is a result of the immunostimulation caused by the

stimulated lymphocytes of Hiserodt (page 9, lines 14-21), and the stimulated lymphocytes "provide cytokines which are effective in recruitment, activation, or stimulating the interaction of host immune cells. The cytokine mixture produced is superior to a cytokine provided in isolated form, or via a transduced cell" (page 10, lines 23-26). Applicants respectfully traverse the rejection for reasons of record.

However, in order to advance prosecution and solely to more clearly describe the subject matter of the invention, and without acquiescence, the Applicants have amended claim 1 to recite a tumor vaccine comprising "at least one isolated cytokine, at least one isolated compound that is a cytokine-inducing agent, or a combination thereof." Similarly, claim 6 has been amended to recite "a tumor vaccine for use in combination with at least one isolated cytokine...."

Hiserodt requires the use of a lymphocyte cell population in their cancer immunotherapy to provide the disclosed immunoactivation. Accordingly, Applicants submit that the instant claims are distinguished from Hiserodt because Hiserodt does not teach or suggest a tumor vaccine comprising a microparticle of the claims and at least one isolated cytokine, at least one isolated compound that is a cytokine-inducing agent, or a combination thereof.

Because Hiserodt does not teach or suggest the Applicants' claimed invention, Applicants respectfully request that the Office Action withdraw the rejection to claims 1-3, 6, and 7 under 35 U.S.C. 102(b). New claims 17-19 depend from claim 1 and therefore should also not be rejected over the cited document.

Golumbek or Pardoll

Claims 1, 2, 4-6, and 8-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Golumbek et al. (Cancer Res. 53: 5841-5844, 1993) ("Golumbek"), or U.S. Patent No. 5,861, 159 to Pardoll et al ("Pardoll"). Claims 3 and 7 are not included in the rejection. The Office Action asserts that based on the definition of microparticle as "a very small particle" in Merriam-Webster Online dictionary downloaded on March 13, 2005 at www.m-w.com, and the definition of "lysate" as discussed above, claims 1, 2, 4-6, and 8-16 are broadly interpreted by the Office Action as drawn to a tumor vaccine comprising two main components of (1) at least one cytokine and (2) tumor material selected from the group consisting of a tumor tissue, a tumor cell, and a component thereof. The Office Action asserts that claims 4, 8, 9, and 13 specify that the cytokine of the base claims are in a controlled-release form, and claims 5-12, and 14-16 specify that the cytokine of the base claims are GM-CSF.

The Office Action asserts that Golumbek teaches "GM-CSF containing microspheres to act as an adjuvant when mixed with irradiated tumor cells prior to immunization" (page 5841, right column, lines 7-8). The Office Action also asserts that Pardoll teaches a pharmaceutical composition comprising controlled release vehicle containing GM-CSF and a tumor antigen. The Office Action alleges that the tumor cells disclosed in the art cited meet the limitation of "microparticles" or "lysate" because the tumor cells are very small particles or in a state of dispersion in an aqueous solution. Also, the Office Action asserts that Pardoll teaches a pharmaceutical composition comprising controlled release vehicle containing GM-CSF and a tumor antigen, for

example, in claim 10. Applicants respectfully traverse the rejections for reasons of record.

However, in order to advance prosecution and solely to more clearly describe the subject matter of the invention, and without acquiescence, the Applicants have amended the claims to recite "a microparticle comprising a fragment of solidified tumor tissues or cells, said fragment being of a size so as to allow phagocytosis of the fragment."

Applicants submit that the claims are distinguished from the cited references because Golumbek and Pardoll do not teach or suggest a microparticle comprising a fragment of solidified tumor tissues or cells, said fragment being of a size so as to allow phagocytosis of the fragment.

For example, Golumbek's and Pardoll's irradiated cancer cells do not encompass a microparticle comprising a fragment of solidified tumor tissues or cells, said fragment being of a size so as to allow phagocytosis of the fragment. Also for example, the tumor antigen of Pardoll's claim 10 is not a microparticle comprising a fragment of solidified tumor tissues or cells, said fragment being of a size so as to allow phagocytosis of the fragment.

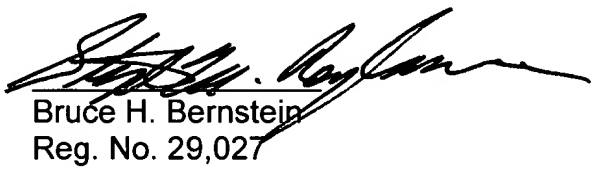
Because Golumbek and Pardoll do not teach or suggest the Applicants' claimed invention, Applicants respectfully request that the Office Action withdraw the rejection to claims 1, 2, 4-6, and 8-16 under 35 U.S.C. 102(b). New claims 17-19 depend from claim 1 and therefore should also not be rejected over the cited documents.

CONCLUSION

For the foregoing reasons, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested.

If the Examiner has any questions, or wishes to discuss this matter, the Examiner is respectfully invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,
Tadao OHNO et al.



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